PATENT
ATTORNEY DOCKET NO. 00786/405004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Denise Faustman	Confirmation No.:	1752
Serial No.:	10/577,891	Art Unit:	1644
§ 371(c) Date:	December 14, 2006	Examiner:	Michail A. Belyavskyi
Customer No.:	21559		
Title:	HOX11+, CD45- CELLS AND METHODS OF ORGAN REGENERATION USING THE SAME		

DECLARATION OF DENISE FAUSTMAN, M.D., Ph.D.

I declare:

1. I am the named inventor of the subject matter described and claimed in United States Patent Application Serial No. 10/577,891 (the "'891 application"), which was filed on April 28, 2006, and granted a 35 U.S.C. § 371(c) date of December 14, 2006.

2. I am an Associate Professor of Medicine at Harvard Medical School and Director of the Immunobiological Laboratories at the Massachusetts General Hospital. I am also a member of the American Association for the Advancement of Science and co-editor in chief of the Journal of Women's Health. In addition, I am a senior author of over 100 peer-reviewed publications in internationally recognized scientific journals.

3. I have read and understood the Office Action dated December 14, 2010. This Declaration is presented to overcome the rejection of claims 146, 148-150, and 159-162 under 35 U.S.C. § 102 for anticipation by Furcht et al. (U.S. Patent No. 7,015,037; hereinafter "Furcht") and Yilmaz (U.S. Patent No. 7,510,877; hereinafter "Yilmaz").

4. I have reviewed Furcht and its statement that multipotent adult stem cells (MASCs) can be isolated from bone marrow, kidney, liver, and brain. Researchers working under my direction have examined bone marrow, kidney, liver, and tonsil tissue from adult human patients for Hox11 expression and, as shown in Exhibit A, none of these tissues demonstrates positive expression of Hox11. Hox11 expression also appears to be absent from brain tissue (see Watt

(Gene 323:89-99, 2003). In contrast, tissue from the spleen of human male and female patients exhibits clear staining for Hox11 expression. β-actin staining was used as a positive control. Thus, none of the tissue sources identified by Furcht for MASCs exhibits Hox11 expression.

5. I have reviewed Yilmaz and its disclosure of hematopoietic stem cells (HSCs) that express CD150+ and lack expression of CD48 and CD244 (Abstract). HSCs are understood in the art to be CD45+ cells and CD45+ splenocytes were known in the art to constitute the majority of cells in the spleen. Thus, one of skill in the art would not necessarily have recognized Yilmaz's CD150+, CD48-, CD244- cells to be CD45- cells. Furthermore, prior to the present application, it was not recognized that the spleen included Hox11+, CD45- cells (see, e.g., Dear et al., *Development* 121:2909-2915, 1995). Finally, Wilson and Trumpp (*Nat. Rev. Immunol.* 6:93-106, 2006) show that CD150+, CD48- HSCs mobilized from the spleen are CD45+. Thus, one of skill in the art would not necessarily have recognized that a Hox11+, CD45- cell was even present in the spleen or could be mobilized from the spleen based on Yilmaz.

6. All statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application and any patents issued thereon.

4/14/11
Date

Denise Faustman, M.D., Ph.D.

Exhibit A

Hox11 Expression in Adult Patients